IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

IN THE MATTER OF THE ADMINISTRATIVE INSPECTION OF: PHARMERICA N29W23721 WoodGate Ct. Pewaukee, Wisconsin, 53207 BEAVER DAM CARE CENTER 410 Roedel Court Beaver Dam, Wisconsin, 53916 COLONY OAKS CARE CENTER 601 Briar Cliff Dr. Appleton, Wisconsin, 54915 HERITAGE SQUARE 5404 W. Loomis Rd. Greendale, Wisconsin, 53129 MT. CARMEL MILWAUKEE 5700 W. Layton Ave. Greenfield, Wisconsin, 53220 VILLAGE GARDENS 1640 Shawano Ave. Green Bay, Wisconsin, 54303 WOODSTOCK HEALTH AND REHAB 3415 Sheridan Rd. Kenosha, Wisconsin, 53140	) Affidavit and Application for) Administrative Inspection Warrant) Under Section 510 (21 U.S.C. § 880) of the) Controlled Substances Act) (P.L. 91-513)

09-M-0261

TO: United States Magistrate Judge Patricia J. Gorence
United States District Court
Eastern District of Wisconsin

The undersigned, being duly sworn, deposes and states as follows:

1. The affiant, Kathy L. Federico, is a duly appointed Diversion Investigator of the United States Department of Justice, Drug Enforcement Administration ("DEA"), and has been assigned to the Milwaukee District Office for fifteen years.

2. Pursuant to the Sections 878(a)(2), 880(b) and 880(d) of Title 21 United States Code (U.S.C.), and Section 3, Appendix to Subpart R, Title 28, Code of Federal Regulations (C.F.R.), your affiant is authorized to execute Administrative Inspection Warrants for the purpose of inspecting controlled premises and/or persons and firms registered under the Controlled Substance Act (21 U.S.C. § 800 *et seq.*), and for the purpose of inspecting, copying, seizing and verifying the correctness of all records, reports, and other documents required to be kept or made under Title 21 U.S.C. § 827 and Title 21 C.F.R. § 1304.01 *et seq*.

3. Since at least September 1, 2005, PharMerica Inc. ("PharMerica") has operated a retail pharmacy in the Eastern District of Wisconsin, which is located at N29 W23721 Woodgate Court, Pewaukee, Wisconsin. This location is a "controlled premise" within the meaning of Title 21 U.S.C. § 880 and Title 21 C.F.R. § 1316.02(c). PharMerica's primary business is to provide pharmacy services and prescription medication to patients in long-term care settings.

4. On September 1, 2005, PharMerica became registered with the Attorney General under 21 U.S.C. §§ 822 and 823 (DEA Registration Number BP9444136), authorizing it to dispense controlled substances in schedules II-V.

5. Pursuant to Title 21 U.S.C. § 827 and Title 21 C.F.R. § 1304.01 *et seq.*, PharMerica is required to keep on the controlled premises complete and accurate records

of all controlled substances received, sold, dispensed, administered, or otherwise disposed of for the last two-year period.

6. Sufficient probable cause for the issuance of an inspection warrant exists if the affidavit established that either the registrant had never been inspected before; See *Matter of Searches and Seizures Conducted on October 2 and 3, 1980*, 665 F. 2d 775, 777 (7th Cir. 1981); *United States v. Acklen*, 690 F.2d 70 (6th Cir. 1982); that a substantial period has passed since the registrant was last inspected; *United States v. Osborne*, 512 F.Supp 413 (E.D. Tenn. 1980); *United States v. Greenberg*, 334 F. Supp 364 (W.D. Pa. 1971); that the registrant has recently received an inordinately large supply of controlled substances; *Matter of Searched and Seizures Conducted on October 2 and 3, 1980*, supra; or that the registrant has committed other suspicious actions. *United States v. Greenberg*, supra.

7. Your affiant has examined the files and records of the Drug Enforcement Administration in the Milwaukee District Office and has determined that with the exception of the events of May 13, 2009 (described below), an inspection of PharMerica has not previously been conducted. Therefore, your affiant seeks authority to inspect PharMerica's Pewaukee location. In addition, your affiant seeks an administrative inspection warrant for the above-captioned nursing homes because they are believed to possess stocks of controlled substances provided to them by PharMerica for use in an emergency situation, and maintained by the nursing homes in emergency "kit boxes." Therefore, your affiant seeks authority to inspect each of the locations at which these emergency stocks are currently maintained (the long term care facilities listed above) for the purpose of conducting a physical inventory of the controlled substances contained in

these emergency boxes, and to seize all required records related to the maintenance and distribution of the controlled substances kept in the boxes. The circumstances surrounding PharMerica's dispensing of controlled substances to the nursing homes are described below.

8. In approximately May 2009, the DEA received a telephone call from a Source of Information ("SOI") stating that PharMerica was routinely violating federal regulations, in part by dispensing Schedule II controlled substances on an emergency basis to numerous Long-Term Care Facilities, including Skilled Nursing Facilities and Adult Family Homes. The information provided by the SOI is believed to be reliable because it has been corroborated by independent sources of information, including PharMerica records documenting the transfer of controlled substances to long term care facilities. According to the SOI, many of these "emergency" prescriptions were dispensed in violation of federal law because PharMerica failed to secure the appropriate oral authorization of a prescribing individual practitioner for the emergency prescription, and/or because PharMerica failed to obtain a written prescription within seven days as required by Title 21, C.F.R. § 1306.11(d)(outlining the procedure for issuing emergency prescriptions), in violation of Title 21 U.S.C. § 842(a)(5).

9. On May 13, 2009, two DEA representatives, including Diversion Investigator Tom Hill, presented a Notice of Inspection to PharMerica and discovered various records on the Pharmacy Operations Manager's desk that appeared to be Schedule II controlled substances prescriptions. In reviewing the prescriptions, the DEA representatives observed that the prescription forms failed to contain a physician's signature, as required by Title 21 C.F.R. § 1306.05. Diversion Investigator Hill requested

that PharMerica mail copies of these documents to the DEA, and the company agreed that it would do so. No additional records were reviewed and no controlled substance accountability audit was conducted at that time.

10. On May 20, 2009, the DEA received the above-stated records from Melissa Maupin, General Manager for PharMerica in Pewaukee, Wisconsin. The records received were divided into various sections. Each section contained a brief handwritten explanation of the records contained within that section. The following are the handwritten descriptions for each category of documents provided by Ms. Maupin on behalf of PharMerica:

> "These are billing sheets that have been faxed and signed script obtained"
>
> "These are billing sheets for emergency kit usage that we need to obtain signed scripts for (Rx's exhausted before posted)"
>
> "Reconciled emergency kit usage sheets"
>
> "Active file – still working to get reconciliation of usage (unrecorded emergency kit usage)"
>
> "Police Report filed for Missing Oxy 40-Nurse dropped box and could not find. DEA 106 to follow"
>
> "These are billing sheets for emergency kit usage that we need to obtain signed scripts for"
>
> "These are billing sheets that need to be recalled to get signed scripts"
>
> "These are billing sheets for emergency kit usage that we matched with signed scripts"

11. Your affiant reviewed the above stated records and noted several regulatory violations. For example, your affiant reviewed an unsigned emergency prescription form for a schedule II controlled substance issued on May 3, 2008, to patient

SL, a resident at the Mt. Carmel Nursing Home in Milwaukee. The form reflects that on May 3, 2008, the nursing home dispensed one Fentanyl 25 mcg/hr patch to SL from an emergency kit provided by PharMerica to the nursing home for use in an emergency situation. As of May 20, 2009, however, PharMerica had not obtained an original written prescription as required by 21 C.F.R. § 1306.11(d). In addition, in reviewing the records provided by PharMerica on May 20, 2009, your affiant noted that: (a) PharMerica failed to maintain complete and accurate records of controlled substances dispensed as required by Title 21, C.F.R. § 1304.21, in violation of Title 21 U.S.C. § 842(a)(5); and (b) PharMerica failed to notify the DEA of a significant theft or loss within one business day as required by Title 21 C.F.R. § 1301.76, in violation of Title 21 U.S.C. § 842(a)(5).

12. Based on the foregoing circumstances, there exists a valid public interest in the effective enforcement of the Controlled Substance Act and its implementing regulations sufficient to justify the inspection of PharMerica to verify the correctness of inventories, records, reports, controlled substances dispensed, controlled substances inventories and other documents that are required to be kept under the Controlled Substance Act. In addition, your affiant seeks authority to copy or seize such documents and things as are necessary to verify the correctness of these required records, and to determine whether records may have been altered after the DEA's visit to PharMercia on May 13, 2009.

13. The SOI also advised your affiant that PharMerica regularly provides emergency kits, which consist of boxes containing controlled substances, to long term care facilities for use in an emergency situation, typically when a physician is not immediately available to issue a valid prescription. However, to comply with federal

law, any such emergency prescription must meet the requirements for a valid emergency prescription set forth in 21 C.F.R. §§ 1306.11 and 1306.21. In addition, both the DEA registrant (PharMerica), and the long terms care facilities must keep accurate records of the disposition of the controlled substances. *See* Title 21 U.S.C. § 827 and Title 21 C.F.R. § 1304.01 *et seq.* (recordkeeping requirements for DEA registrants) *and* Wisconsin Examining Board Regulation Phar 8.11(3)(requiring that a "pharmacist shall be responsible for proper control and accountability for such emergency kits within the LTCF [long term care facility] which includes the requirement that the LTCF and the providing DEA registered hospital, pharmacy or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kits, the disposition of those controlled substances, plus the requirement to take at least monthly physical inventories"). Therefore, the long term care facilities which receive emergency kit boxes from PharMerica, although not registered with the DEA, are "controlled premises" under 21 U.S.C. § 880(a)(1) because they are "places where original or other records or documents required under [the CSA] are kept."

14. The SOI has advised your affiant that PharMerica regularly provides emergency kit boxes, along with forms documenting the disposition of the medications in those kits, to several long term care facilities, including Beaver Dam Care Center, Colony Oaks Care Center, Heritage Square, Mt. Carmel Milwaukee, Three Oaks at Marshfield, Woodstock Health and Rehabilitation Center, Village Gardens, and Wisconsin Dells Health and Rehabilitation Center. For example, the SOI stated that for the past two years, Three Oaks Nursing Home, 209 Wilderness View Drive, Marshfield, Wisconsin, has maintained an Automated Dispensing System ("ADS") containing approximately 24

types of Schedule II-IV controlled substances. This system, which consists of a secure emergency "kit box" containing controlled substances, permits long term care facilities to obtain controlled substances for its residents on an emergency basis. However, the SOI stated that to his/her knowledge no dispensing information from the ADS has been entered into Pharmerica's controlled substance dispensing computer system since October 2008, a potential violation of Title 21 U.S.C. § 827 and Title 21 C.F.R. § 1304.01 *et seq.* (recordkeeping requirements for DEA registrants).

15. On June 22, 2009, your affiant conducted a search of the Controlled Substance Registration System, which contains records of all DEA registrants, and determined that (a) PharMerica has not obtained a DEA Registration for the above ADS as required by 21 C.F.R. §1301.27; (b) PharMeria failed to complete a DEA Schedule II Order Form for the distribution of Schedule II controlled substances from the ADS as required by 21 C.F.R. § 1305.03; and (c) PharMerica failed to obtain prescriptions for the dispensing of controlled substances from the ADS, as required by Title 21 C.F.R. § 1304.04. Therefore, your affiant seeks authority to inspect each of the locations at which these emergency kit boxes are currently stored (the long term care facilities listed above) for the purpose of conducting a physical inventory of the controlled substances contained in these emergency boxes, and to seize all required records related to the maintenance and distribution of the controlled substances kept in the boxes.

16. Your Affiant states that the inspections of PharMerica and the long term care facilities listed above will be conducted within regular business hours; that the Investigator's credentials will be presented to the registrant; that the inspection will begin as soon as practicable after the issuance of the warrant and will be completed with

reasonable promptness; and that the warrant will be returned within ten (10) days to a Magistrate Judge for the United States District Court for the Eastern District of Wisconsin. The inspection of PharMerica will include the inspection and copying of inventories, records, dispensation logs, reports, prescriptions, order forms, invoices, and other documents required to be kept for the verification of the records, reports, and documents required under the Controlled Substances Act and/or the seizure of such records. The inspection of PharMerica will also extend to the inspection and seizure of stocks of controlled substances, finished and unfinished substances, and pertinent equipment associated with the storage and handling of controlled substances. The inspections of the long term care facilities will be limited to an inspection of all contingency or emergency stocks of controlled substances provided to the facility by PharMerica, and to the seizure of records relating to the purchase, sale, dispensing or other transfer of such contingency or emergency stocks of controlled substances.

17. The term records includes all of the foregoing items of evidence in whatever form and by whatever means they may have been created or stored, including any electrical, electronic, or magnetic form. The term records also include any computers on the premises of PharMerica (including file servers, desktop computers, laptop computers, mainframe computers, and storage devices such as hard drives, Zip disks, and floppy disks). The DEA also seeks authority to secure copies of any relevant electronic records by making forensic images of the hard-drives of relevant PharMerica computers or computer systems. With respect to the long term care facilities described above, the DEA seeks limited authority to secure copies of any relevant electronic records by making forensic images of the hard-drives of relevant computers or computer systems

which may contain information pertaining to the dispensing of controlled substances from the emergency kit boxes or ADS machines provided by PharMerica to the long term care facilities.

18. Your Affiant has verified and has personal knowledge of the facts contained in this affidavit and they are true to the best of her knowledge and belief.

Kathy L. Federico
Diversion Investigator
Drug Enforcement Administration

Sworn to before me and subscribed in my presence on the 20th day of July 2009.

Patricia J. Gorence
United States Magistrate Judge
United States District Court for the
Eastern District of Wisconsin